In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-200V
(not to be published)

MARIO CARUSO, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Filed: October 18, 2017 Decision; Denial of Entitlement; Acute Disseminated Encephalomyelitis ("ADEM"); Influenza ("flu") Vaccine; Onset; Third Althen Prong

Joseph Pepper, Conway Homer, P.C., Boston, MA, for Petitioner.

Darryl Wishard, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On March 2, 2015, Mario Caruso filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]). Petition ("Pet.") (ECF No. 1). Petitioner alleges that he developed acute disseminated encephalomyelitis ("ADEM") as a result of the trivalent influenza "(flu") vaccine he received on October 16, 2012. Pet. at 1. An entitlement hearing was held in Washington, DC, on April 20-21, 2017.

[1] Although this decision has not been designated for publication, it will nevertheless be posted on the United States Court of Federal Claims' website, and in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

After considering the record as a whole, and for the reasons explained below, I find that Petitioner has not carried his burden of proof. The two-month gap between vaccination and the December 2, 2012 onset of symptoms most credibly connected to Petitioner's subsequently-diagnosed ADEM is too attenuated temporally to establish a medically acceptable timeframe for vaccine-induced ADEM. In addition, although ADEM is usually understood to be acute (especially when a vaccine is most plausibly implicated in its development), Petitioner experienced an atypical form of the disease which evolved over time, only becoming acute a month *after* onset – but Petitioner did not establish that the same reliable science associating certain vaccines with the classic form of ADEM would still apply under the facts of this case.

I. Factual Background

Vaccination and Alleged Initial Symptoms

Mr. Caruso received the flu vaccine on October 16, 2012, when he was 64 years old. Ex. 1 at 1. His pre-vaccination medical history included prostate enlargement, hypolipoproteinemia,[3] varicose veins of the lower extremity with an ulcer, and sclerosis of the skin.[4] Ex. 2 at 1; Ex. 5 at 9.

There are no medical records from the ensuing ten weeks establishing or suggesting that Mr. Caruso experienced any immediate reaction to the vaccine. Thus, on October 23, 2012, Petitioner visited his physician at Peachwood Medical Group ("PMG"), in Clovis, California, to have his lipid levels checked, and he did not then report any neurological issues or other symptoms. Ex. 2 at 7, 12.[5] Nevertheless, Mr. Caruso has alleged that in this post-vaccination time period he began to experience symptoms connected to his later-diagnosed neurologic injury. *See generally* Petitioner's Affidavit, dated March 5, 2015, filed as Ex. 17 (ECF No. 7). In support, Petitioner offered not only his own prior written statements, but the live hearing testimony of his wife, Sylvia Caruso, and daughter, Kristy Caruso. *See generally* Transcript ("Tr.") at 6-69, 70-90.

Mrs. Caruso testified that in November 2012, she and her husband moved from Kingsburg, California, to Clovis, California. *See generally* Ex 24. At that time, she began to notice some changes in his behavior. *Id.* at 1-2. Specifically, during the first week of November 2012, Mrs. Caruso and Ms. Kristy Caruso noticed Petitioner uncharacteristically struggling to move large items, and becoming extremely fatigued when he did so. Ex. 25 at 1; Tr. at 73-75. Mrs. Caruso

[3] Hypolipoproteinemia is a term used to note the presence of abnormally low levels of lipoproteins in the serum. *Dorland's Illustrated Medical Dictionary* 903 (32d ed. 2012) (hereinafter "*Dorland's*").

[4] Sclerosis is evidenced by a hardening of the skin, an increased formation of connective tissue, or disease of the interstitial substance. *Dorland's* at 1680.

[5] The lipid check that was performed showed high levels of glucose, triglycerides, and LDL cholesterol. Ex. 2 at 12.

also recalled that during this general time frame (November-December 2012), Petitioner seemed to be having difficulty with his vision, often closing one eye to focus when he drove or watched television. Ex. 24 at 1-2; Tr. at 13. Mr. Caruso's symptoms became progressively worse until the end of December, when his family noticed (during a birthday celebration for his other daughter, Gina) that he was walking in an unstable way, as he if were drunk (although the testifying fact witnesses all maintained that he had not been inebriated at the time).[6] Ex. 24 at 1-2, Ex. 25 at 1-2; Tr. at 16-17, 76-77. Around this time, Mrs. Caruso shared her concerns about Petitioner's health with Ms. Kristy Caruso. *Id.* at 76-77.

January 2013 Incident and Initial Treatment

In late January 2013, Petitioner experienced a more acute incident that encouraged him to seek medical intervention. As Mrs. Caruso related at the entitlement hearing, she and Petitioner were shopping on a Friday, and as they were walking through a Walmart parking lot, Mr. Caruso "suddenly" was "just walking totally weird." Tr. at 18. His feet dragged, and he appeared to display an uneven gait like a "drunken sailor." *Id.* Mrs. Caruso used a shopping cart to stabilize Mr. Caruso, and when they returned home she expressed to him her concern that his symptoms warranted a doctor's visit as soon as possible. *Id.* at 19.

Mr. Caruso made an appointment with his primary caregiver at PMG, nurse practitioner Cynthia Baer, for January 28, 2013. *See* Ex. 16 at 1. The Carusos informed Nurse Practitioner Baer that Petitioner was "walking funny," and that his gait problems had begun the month before (meaning December 2012), ebbing then recurring on the prior Friday (January 25th), at which time he had experienced "really wobbling" legs. *Id.* at 1, 8. Mr. Caruso denied any paresthesias, but felt off balance. *Id.* at 8. He also had been falling asleep in the evenings for the past month. *Id.*

These initial medical records do not mention any symptoms occurring prior to December 2012. Indeed, in the "review of systems" section of the medical record from this January 28th visit, Petitioner denied experiencing blurred vision, double vision, photophobia, headaches, and weakness (several of which would be included in the symptoms that Mrs. Caruso and Ms. Kristy Caruso claim Petitioner had experienced in November 2012). Ex. 16 at 8. The results of a complete exam were deemed normal, but Nurse Practitioner Baer noted that Mr. Caruso seemed "to slightly drag right tow [sic]. No specific abnormality but gait does not seem totally normal." *Id.* at 9. Ultimately Petitioner was diagnosed with dizziness and a gait disorder, and diagnostic tests were ordered. *Id.* at 12. A CT scan performed on Petitioner's brain on February 1, 2013 found no significant abnormalities, with the technician deeming the results "unremarkable." Ex. 11 at 1.

[6] It appears that in the gap in medical records from October 2012 - January 2013 Mr. Caruso had his appendix removed. This is noted in his surgical history at his January 28, 2013 visit, but not at either of his visits to PMG in October 2012. Ex. 16 at 2. No records involving this procedure were filed.

Treater Consensus on ADEM Diagnosis

On February 8, 2013, Mr. Caruso returned to PMG complaining of dizziness, diplopia, and gait difficulty, and was seen by Dr. Lee Copeland. Ex. 2 at 15. At that visit, and with his wife again present, Petitioner repeated his representation from January that he had first experienced such symptoms for a period of time of slightly greater than one month, and the Carusos expressed their concerns about the nature of his symptoms. *Id*. at 20. Dr. Copeland included multiple sclerosis ("MS") or "other progressive neuro deficit" in the differential diagnosis and referred the Carusos to a neurologist. *Id.*

A few days later, on February 11, 2013, Mr. Caruso saw neurologist Dr. Loveneet Singh. Ex. 5 at 9-10. The Carusos again reported that Petitioner's symptoms had been ongoing for "approximately a month," but had become progressively worse. *Id.* at 9. Mr. Caruso now complained of fatigue, vision changes with diplopia, and gait problems with stumbling and dragging of his left foot. *Id*. Mrs. Caruso reported that Petitioner was slower to respond verbally to her, and that his voice had become softer. *Id*. At this visit, Mr. Caruso displayed impaired coordination and diplopia, as well as an inability to perform rapid alternating movements. *Id*. His gait was slow, and he required support when walking. *Id*.

Based upon the physical examination, Dr. Singh opined that Mr. Caruso demonstrated evidence of upper motor neuron dysfunction, including cerebellar signs and gait ataxia.[7] Ex. 5 at 10. Subsequent testing confirmed Dr. Singh's impressions. Thus, brain and cervical spine MRIs performed on March 2, 2013, showed multifocal signal abnormalities in the midbrain, brainstem, brachium pontis, cerebellum, and spinal cord. *Id.* at 42. Some of the lesions enhanced,[8] and some cerebral volume loss was noted. These imaging studies also showed both enhancing and non-enhancing signal abnormalities. *Id.* at 40, 42; Ex. 11 at 2-3, 5-6; *see also* Ex. 14 at 41. Evidence of what appeared to be active inflammation in Petitioner's spine suggested "active demyelinated plaques with breakdown of the blood brain barrier." Ex. 11 at 2-3.

Mr. Caruso saw Dr. Singh again on March 11, 2013. By this time, ADEM and MS were both included in the differential diagnosis. Ex. 5 at 8. Dr. Singh also noted that Petitioner's symptoms had been preceded by a vaccination. *Id.* In an attempt to home in on the correct explanation for Petitioner's symptoms, Dr. Singh ordered more testing, including lab work to show glucose and protein levels, a cell count, and an MS panel. *Id*. The results of this testing were largely

[7] Gait ataxia is characterized by irregular muscular action when walking. *Dorland's* at 170.

[8] Lesion enhancement on MRI occurs after the uptake in the lesion of a Gadolinium-based contrast agent injected into a subject's blood. *W.C. v. Sec'y of Health & Human Servs.,* 100 Fed. Cl. 440, 444 (2011). It reveals a breakdown of the blood-brain barrier (since the contrast agent is able to go into the brain). Such a breakdown can trigger neurological injury, by allowing infectious or inflammatory agents into the brain and central nervous system, causing damage. Tr. at 110-12.

normal, however, including no evidence of oligoclonal bands (commonly associated with MS), and a negative MS panel otherwise. *Id.* at 26.

On March 11, 2013, Mr. Caruso obtained treatment from an ophthalmologist, Dr. Gary Walters, at Eye Medical Center in Fresno, California. Dr. Walters informed Dr. Singh of his findings on March 19, 2013, noting Petitioner's sudden onset of double vision and walking difficulties were reported to have begun to two months earlier (thus again placing onset of symptoms no earlier than January 2013). Ex. 2 at 82, *see also* Ex. 7 at 25 ("pt's wife states she noticed he began to close one eye or the other when watching TV or driving around 2 mths ago and then began to notice he was having problems walking"). Mr. Caruso displayed decreased vision (right eye 20/200; left eye 20/70), although some of these symptoms showed improvement later in 2013. Ex. 7 at 27.[9]

Thereafter, Petitioner continued to obtain treatment, and to seek an explanation for his condition. An autosomal dominant ataxia evaluation ordered by Dr. Singh in February 2013 to identify any pathogenic mutations that might explain the ataxia Petitioner was suffering came back negative on March 26, 2013. Ex. 5 at 11-33. Mr. Caruso had a follow-up appointment on April 22, 2013, and was seen by Gloria Lovering, a nurse practitioner working with Dr. Singh. *Id.* at 7. The handwritten record from that visit again referenced his October 2012 flu vaccination, and the diagnostic assessment now included only ADEM and Balint Syndrome.[10] *Id.* Petitioner was instructed to seek physical therapy for his gait problems.

Subsequent Treatment Efforts

Mr. Caruso returned to Dr. Singh in July 2013. By this point, the ADEM diagnosis was deemed confirmed, although no reference is made in these records to the flu vaccine having played a role in its development. Ex. 5 at 5. Mr. Caruso has since continued to obtain treatment for his ADEM/neurologic symptoms. After about a year of ongoing symptoms with no real signs of progression in severity and no evidence of additional developing lesions, Mr. Caruso sought a second neurological opinion on June 23, 2014. Ex. 14 at 49. At that time, he saw Dr. Leslie Dorfman at the Stanford Hospital in Redwood City, California.

Dr. Dorfman discussed Mr. Caruso's medical history up to that point, demonstrating a desire to reevaluate Petitioner's diagnosis in light of the entire medical record generated to that date. Ex. 14 at 49-52. Some of his characterizations of the facts are not consistent with the aforementioned records, however; thus, Dr. Dorfman places onset of Petitioner's symptoms in

[9] Thus, Petitioner's vision improved to 20/100 on the right and 20/50 on the left by May 3, 2013, 20/70 on the right 20/40 on the left by June 3, 2013, and 20/50 on the right and 20/30 on the left by August 5, 2013. Ex. 7 at 7, 13, 1.

[10] Balint Syndrome includes gaze paralysis, ataxia of eye movements, and other vision disturbances usually caused by bilateral lesions in the parietooccipital region. *Dorland's* at 1822.

December 2012, but then indicates that symptoms "came on about a month after he received a [flu] immunization," when in fact the vaccine had been received more than two months prior. *Id.* at 49. Dr. Dorfman otherwise noted that Petitioner had received at some point a "provisional diagnosis" of ADEM, and that his condition had not significantly worsened but also had not improved. *Id.* at 49-50. Dr. Dorfman reviewed the MRIs ordered in 2013 by Dr. Singh, agreeing that they were not indicative of MS. *Id.* at 51.

After a physical examination and consideration of Petitioner's history, Dr. Dorfman proposed that ADEM was an "acceptable working diagnosis," but that he ultimately felt the true classification for his symptoms remained unidentified. Ex. 14 at 51. He therefore proposed some additional diagnostic testing aimed at arriving at a treatment that (if properly targeted at the actual cause of Petitioner's symptoms) would be more effective. *Id.*

A month later, Petitioner returned to Dr. Dorfman on July 25, 2014. *See* Ex. 14 at 47-48. Dr. Dorfman noted that the testing he had requested had produced negative or normal results, and that additional review of his 2013 MRIs by other neuro-radiologists had produced no novel insights. *Id.* at 47. Dr. Dorfman thus opined that Mr. Caruso likely was suffering from an "atypical form" of ADEM, offering no views as to its etiology, and recommended a steroid treatment, followed by IVIG[11] if the steroids proved ineffective. *Id.* at 47-48. By August (when Petitioner sought treatment for pneumonia secondary to an incident of acid reflux), Mr. Caruso reported some improvement from the steroid treatment, leading Dr. Dorfman to propose its continuation (while still allowing for possible IVIG). Ex. 34 at 4-5.

Additional medical records indicate that Mr. Caruso has since continued to experience sequelae from his 2012-2013 symptoms. *See, e.g.*, Ex. 29 at 22-24, Ex. 33 at 1-2. Some of these records suggest a relationship between the flu vaccine and Petitioner's symptoms, but it appears from those same records that the memorialized associations represent less the conclusions of treaters and more the recitation of Mr. Caruso's medical history made to them by Petitioner or his spouse – recitations which differ from the contemporaneous information provided to treaters in January 2013, after his initial gait problems led him to seek treatment. *See, e.g.*, Ex. 33 at 1-2 (notes from August 3, 2015, visit with neurologist identifying gait problems as beginning in November 2012, and an onset of other symptoms on January 1, 2013). MRIs performed in April 2015 appear to have confirmed that no additional lesions had appeared since 2013, thus further corroborating the accuracy of the ADEM diagnosis (Ex. 22 at 1-5).

[11] Intravenous immunoglobulin ("IVIG") is a blood product used to treat patients with antibody deficiencies, including neurological disorders. *Clinical Uses of Intravenous Immunoglobulin*, NCBI (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/ (lasted visited on Aug. 28, 2017). It is commonly prescribed to treat diseases believed to be autoimmune in nature, increasing the effectiveness of an individual's immune response.

II. Hearing Testimony

A. *Fact Witnesses*

As already noted, Mr. Caruso's wife and daughter both testified at the entitlement hearing. Their testimony was largely consistent with the factual summary above. Tr. at 6-90. Thus, they attempted to corroborate Petitioner's claim that onset of his symptoms began in November 2012, two months before he sought formal medical treatment. Mrs. Caruso recalled that the most noticeable symptom after Petitioner's receipt of the flu vaccine was that he squinted one eye to drive causing him to drive erratically. Tr. at 10. She remembered this pattern of driving occurring around the first week of November. *Id*. In addition, both fact witnesses testified to noticing his fatigue during the first week of November when Petitioner and his wife were moving to a new house. Tr. at 11, 75. Thereafter, Mrs. Caruso observed changes in his daily routine due to sleepiness and fatigue. *Id*. at 12, 76.[12]

Mrs. Caruso also described the worsening of Petitioner's symptoms and the concern expressed by Dr. Singh about the lesions observed from MRIs. In addition, Mrs. Caruso recalled that Dr. Singh suggested at Petitioner's March 11, 2013, visit that whatever was going on could have been related to the flu vaccine (although there is no medical record corroborating this alleged statement). Tr. at 27. Around this time, Mrs. Caruso began maintaining a journal documenting the symptoms she noticed as well as the various doctors' visits. *See generally* Ex. 39. The journal (filed right before the hearing in April 2017) contains an entry from March 2013 stating that Mr. Caruso's squinting at the TV and while driving had begun "about November and into December." *Id.* at 1 (March 9, 2013 entry). However, Mrs. Caruso conceded on cross examination that at most initial treater visits she identified onset as occurring *after* the shopping incident in late January, explaining that she had not realized at the time that there might be a correlation between his gait issues and other symptoms. Tr. at 47.

B. *Petitioner's Expert – Dr. Carlo Tornatore*

Dr. Tornatore provided an initial report as well as a supplemental report reacting to objections raised by Respondent about the onset of Petitioner's symptoms, and testified at hearing. *See e.g.*, Exhibit 26, filed Nov. 24, 2015 (ECF No. 22) ("Tornatore Rep."); Exhibit 28, filed Mar. 29, 2016 (ECF No. 29) ("Tornatore Supp. Rep."); Tr. 97-187, 249-258.

Dr. Tornatore is a board-certified neurologist. *See* Exhibit 27, dated Nov. 24, 2015 ("Tornatore CV"). He graduated from Cornell University with Bachelor of Arts in Neurobiology, and then attended Georgetown University Medical Center where he received a Master of Science

[12] Kristy Caruso acknowledged that she had less day-to-day insight into the course of her father's symptoms than Mrs. Caruso, stating that outside of the moving event and birthday celebration, she had not noticed her father's symptoms despite spending the holidays with Petitioner and Mrs. Caruso. Tr. at 85.

in Physiology. *Id.* at 2; Tr. at 98. He subsequently graduated from medical school at Georgetown University School of Medicine, completed a residency in the Department of Neurology at Georgetown University Hospital, and completed a fellowship in molecular virology at the National Institutes of Health in Bethesda, Maryland. Tornatore CV at 2; Tr. at 98. *Id.* He has published articles addressing cell biology and pathology of demyelinating disorders. Tornatore CV at 7-14. Currently, he serves as Vice Chairman in the Department of Neurology at MedStar Georgetown University Hospital and as a Professor of Neurology at Georgetown University Medical Center. Tornatore CV at 3; Tr. at 98-99. At hearing, Dr. Tornatore represented that he is an immunologist as well – but, although he plainly has training in the field and was competent to testify about it, this is not his specialty, and his CV does not reflect a learned focus on the subject. Tr. at 98.

Dr. Tornatore opined that Mr. Caruso's ADEM was triggered by his October 2012 flu vaccination through the process of molecular mimicry. Tornatore Rep. at 12. He explained that vaccination creates an immune response causing self-antigens contained in the brain to be mistakenly destroyed by the immune system because they are homologous to antigens contained in the vaccine. *Id*. According to Dr. Tornatore, these self-antigens can cause an "inflammation cascade" that can damage organs, resulting in a variety of symptoms including motor, sensory, gait, and bladder dysfunction. *Id.* at 13.

Dr. Tornatore could not identify a specific target antigen in the nervous system for the pathogenesis of ADEM. Tornatore Rep. at 12-13. He did, however posit that it was highly probable, given the vast amount of potential antigens in the nervous system, that homology could be found between a nervous system peptide sequence and a vaccine antigen. *Id*. at 13. Alternatively, he proposed that B and T cells could be activated by a vaccine antigen even in the absence of homology. *Id*. Those B and T cells would then mount an autoimmune response leading to ADEM. *Id*.

Dr. Tornatore proposed that Mr. Caruso's ADEM most likely began within a month after receipt of the flu vaccine (or November 2012). Tr. at 175. In so maintaining, however, he relied solely on the affidavit of Mr. Caruso, rather than the contemporaneous medical records. Tornatore Rep. at 13. In his supplemental report, Dr. Tornatore proposed a medical/scientific basis for the acceptability of an ADEM onset that extended beyond 30 days. *See* Tornatore Supp. Rep. at 1, *citing* C.M. Poser, *Neurological Complications of Swine Influenza Vaccination*, 66 Acta Neurology Scandinavia 4:413-31 (1982), filed as Ex. 28, Tab A (ECF No. 29-1) ("Poser"). Poser was a 1982 study of the swine flu vaccine that found onset of autoimmune neurological complications in patients who had received the vaccine occurring between one and 63 days. Poser at 416-21. Dr. Tornatore testified that Poser supported his opinion that a two-month "lag" from date of vaccination to onset had biologic plausibility. Tornatore Supp. Rep. at 1; *see also* Poser at 415. In fact, however, the mean interval set forth in Poser was actually 16.5 days, or a little more than two weeks, with only one case falling outside the proposed two-month timeframe. Poser at 421.

C. *Respondent's Expert – Dr. Thomas Leist*

Respondent's expert, Thomas Leist, M.D., Ph.D., submitted one expert report in this case and testified at the hearing. *See* Ex. A, dated June 16, 2016 (ECF No. 30) ("Leist Rep."); Tr. at 188-248.

Dr. Leist attended the University of Zurich, where he obtained his Ph.D. in immunology and biochemistry as well as a post-doctorate degree in experimental pathologies. Tr. at 188-89; *see also* Ex. B (Leist CV). He also completed a post-doctorate at the University of California, Los Angeles and attended medical school in the United States at the University of Miami. *Id.* He then completed a residency in neurology at Cornell University before becoming a fellow at the National Institute of Health. Tr. at 189. Dr. Leist is board certified in neurology and currently serves as a professor of neurology at Thomas Jefferson University in Philadelphia, Pennsylvania as well as directing the MS center and guiding the MS or the neuro-immunology fellowship program. *Id*. As a part of this role, he sees patients diagnosed with MS (whether solely or as part of a differential diagnosis), as well as seeing patients in tertiary care hospitals affiliated with Thomas Jefferson University Hospital. *Id*. Dr. Leist also treats patients with ADEM. *Id.* at 190-91.

Although Respondent had (as of the time of the filing of the Rule 4(c) Report) initially accepted the accuracy of Mr. Caruso's ADEM diagnosis, Dr. Leist disagreed (and Respondent subsequently revised his formal position in the case in reaction). *See* Tr. at 230; Leist Rep. at 7. Instead, Dr. Leist proposed that Mr. Caruso had first developed unspecified neurological symptoms in late December 2012, experiencing some improvement in January 2013, followed by worsening symptoms in late January/early February 2013. *Id.* at 194. He did not deem this symptoms course to constitute ADEM – although regardless of what Mr. Caruso's illness was, Dr. Leist maintained, it was not vaccine-caused. Tr. at 194-96, Leist Rep. at 7.

In support of his argument, Dr. Leist referenced imaging studies of Mr. Caruso's brain performed in March 2013 showing both enhancing and non-enhancing signal abnormalities - suggesting non-simultaneous accrual of lesions in the central nervous system, with some older than others. Tr. at 194-95; Leist Rep. at 5-6. In ADEM, by contrast, lesions usually appeared abruptly and at the same time. Leist Rep. at 5-6; S. Tenembaum, et al., *Acute Disseminated Encephalomyelitis: A Long Term Follow-Up Study of 84 Pediatric Patients*, 59 Neurology 8:1224-31, at 1224-26 (2002), filed as Ex. 26C (ECF No. 25-1) ("Tenembaum"). Thus, Dr. Leist maintained, the non-enhancing lesions that had also been observed could have occurred prior to the vaccination, and might have been caused instead by a longer-standing process of deterioration consistent with aging or another remote injury. Tr. at 195-96. Dr. Leist further noted that Mr. Caruso's worsening vision, followed by an improvement from March to August 2013, was just as compatible with optic neuritis as ADEM, further diminishing the accuracy of the diagnosis. Leist Rep. at 6; Tr. at 211; Ex. 7 at 6.

Dr. Leist further opined that, even if Mr. Caruso had properly been diagnosed with ADEM, the disease could not have been caused by the flu vaccine. This opinion was largely based on the timing of Petitioner's symptoms. In Dr. Leist's understanding, existing reliable literature only supports a 5 to 28 day interval for causality between *any* kind of vaccine and ADEM. Leist Rep. at 5, 7; Ex. C at 4. An article offered by Respondent, Rowhani–Rahbar, et al., *Biologically Plausible and Evidence–Based Risk Intervals in Immunization Safety Research,* 31 Vaccine 271–77 (2012), filed as Ex. C (ECF No. 30-3) ("Rowhani-Rahbar") goes a bit further, noting that an interval of 2 to 42 days "remains biologically plausible," but expressing uncertainty as to the trustworthiness of that conclusion. Rowhani-Rahbar at 274. Regardless, even 42 days, or six weeks, was beyond the onset period in this case, which exceeded 60 days if measured from the October 2012 vaccination to the earliest onset corroborated by the medical records (late December 2012). *See* Tr. at 28, 155, 194; Ex. 16 at 15.

Dr. Leist also questioned the timing of onset in light of the specific features of ADEM as accepted in the medical and scientific community. An article filed by Petitioner - F. Noorbakhsh, et al., *Acute Disseminated Encephalomyelitis: Clinical and Pathogenesis Features,* 29 Neurologic Clinics 759-780 (2008), filed as Ex. 26B (ECF No. 25-1) (hereinafter, "Noorbakhsh") - stated that "ADEM typically appears with an abrupt onset of neurological symptoms 2 to 30 days" after vaccination. Noorbakhsh at 761. But, Dr. Leist maintained, the medical record did not corroborate such an abrupt onset under *any* fact pattern embraced by Petitioner to explain his course of symptoms. Tr. at 220-21, Leist Rep. at 5-6. Dr. Leist also attacked Poser as unreliable support for Petitioner's onset argument, noting that it involved the swine flu vaccine, cited only case reports, and that it was not referenced in more recent and widely-embraced articles discussing the timeframe for ADEM like Noorbakhsh or Rowhani-Rahbar. Leist Rep. at 4. In addition, although the authors in Tenembaum noted that ADEM was observed as being preceded by vaccination or viral illness in 74 percent of cases, the mean onset stated in the article was 12.1 days – much shorter than in this case. *Id*. at 3.

III. Procedural Background

After initiating this action in March 2015, Mr. Caruso began filing medical records in support of his claim, completing the process three months later. Respondent's Rule 4(c) Report was then filed almost immediately thereafter, on June 3, 2015 (ECF No. 14). Initially, Respondent accepted Petitioner's allegation that he had in fact experienced "atypical" ADEM. Rule 4(c) Report at 10. But Respondent maintained that compensation was not appropriate for Petitioner's injury, questioning both the strength of the evidence supporting the causation theory as well as the appropriateness of the several-month timeframe between vaccination and onset. *Id.* at 11-12.

Petitioner was thereafter ordered to file an expert report, and after obtaining several extensions of time did so on November 24, 2015, with the filing of Dr. Tornatore's first report. *See* ECF No. 22. Respondent raised questions in reaction to Dr. Tornatore's opinion, noting that

he opined that onset of vaccine-induced ADEM was most likely within 30 days of vaccine, but the medical records unquestionably indicated onset no sooner than 60 days from the October 2012 vaccination (although Petitioner and other family members were alleging that they observed neurologic symptoms in November 2012). *See* Status Report, dated November 30, 2015 (ECF No. 24). I subsequently held a status conference, ordering Petitioner to obtain a supplemental report from Dr. Tornatore addressing the onset discrepancy and its impact on his theory. Order, dated December 15, 2015 (ECF No. 26). Petitioner filed that supplemental report on March 29, 2016 (ECF No. 29).

In reaction, Respondent filed Dr. Leist's sole report on June 16, 2016 (ECF No. 30). As noted above, and contrary to Respondent's earlier position, Dr. Leist opined that Mr. Caruso had not experienced ADEM. Leist Rep. at 7; Tr. at 194. The parties thereafter agreed that the matter was appropriate for resolution, and a hearing was set for April 2017. The hearing went forward as scheduled, after which the parties requested an opportunity to file simultaneous post-hearing briefs, doing so on July 28, 2017 (ECF Nos. 49-50). This matter is now ripe for a decision.

IV. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[13] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d

[13] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[14]

[14] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human*

Servs., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528;

see also Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir.

1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered").

ANALYSIS

I. Brief Overview of ADEM

ADEM is formally defined as an inflammatory demyelinating disease of the central nervous system characterized by an acute onset and a monophasic course. Tenembaum at 1224. It features an autoimmune attack on the myelin sheath of the central nervous system, resulting in inflammation and swelling in the brain and spinal cord.[15] When the myelin is damaged, nerve impulses can slow or stop, causing a range of neurological problems.[16] Symptoms can include fever, headache, vomiting, tremors, seizures, and paralysis.[17] The incidence of ADEM is more common in children or young adults.

The signature of ADEM is an abrupt onset typically following (in two to 30 days) an infection, although vaccination has also been associated with the illness. Noorbakhsh at 761. Upon MRI testing, lesions are found in the brain of patients suffering from ADEM, but these lesions resolve, true to the monophasic nature of the disease. *Id*. In very rare instances a patient can have a relapse of ADEM symptoms, but such patients have usually already experienced the abrupt initial onset, and the later symptoms are not accompanied by new or worsened lesions. *Id*.

[15] *Dorland's* at 613; *ADEM Overview*, Nat'l MS Soc'y, http://www.nationalmssociety.org/What-is-MS/Related-Conditions/Acute-Disseminated-Encephalomyelitis-(ADEM) (lasted visited on Aug. 29, 2017).

[16] *Demyelinating Disease: What Can You Do About It?*, Mayo (2017), http://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/expert-answers/demyelinating-disease/faq-20058521 (last visited Aug. 29, 2017).

[17] *Dorland's* at 613.

II. Onset of Mr. Caruso's ADEM Most Likely Occurred in December 2012

Before determining whether Petitioner has carried his overall burden in this case, I must make a fact determination regarding the onset of Petitioner's first ADEM-related symptoms. Petitioner argues for an onset beginning sometime in November 2012 (although Dr. Tornatore allowed for the possibility of a later onset as well as also consistent with his causation theory). Tr. at 114; Ex. 28 at 2. In support, Petitioner offered the testimony of his wife and daughter, both of whom provided anecdotal recollection of incidents that could reflect neurologic problems (*e.g.* weakness, sleepiness, blurred vision) that they witnessed affecting Petitioner as early as November 2012.

Both fact witnesses were credible individuals, and I have no doubt that they made an honest effort to recall experiences or observations that might in retrospect seem connected to Mr. Caruso's later and more obvious neurologic symptoms. But the instances they described are too anecdotal and inconclusive to deem significant (especially without any additional corroborative proof). This is especially the case when their oral recollections are compared with Petitioner's more precisely-documented, medically-tested symptoms referenced in the January and February 2013 medical records. Those records strongly support the conclusion that onset of his symptoms began in December 2012 – as there are several instances in which Petitioner or Mrs. Caruso directly so informed treaters. *See, e.g.,* Ex. 16 at 15; Tr. at 28. Program precedent counsels giving such contemporaneous evidence more weight than after-the-fact witness statements about a prior occurrence. *See Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

The fact witnesses' testimony about a November onset, by contrast, was not sufficiently corroborated by other circumstantial evidence to elevate it over contemporaneous record proof that clearly establishes a later onset date.[18] The only overlap between the two was the contention that Mr. Caruso first began to experience symptoms in December 2012. I therefore find that Petitioner's ADEM-related symptoms began no earlier than late December 2012 (approximately two months after vaccination), as confirmed by witness testimony and corroborated by medical records from around the time Petitioner first sought treatment for his gait problems in late January 2013.

[18] The best corroborative evidence in this regard was Mrs. Caruso's journal, which she began in March 2013. As noted above, the journal does have an entry from early March referencing symptoms beginning in the November-December continuum, and therefore is evidence supporting an earlier onset. Ex. 39 at 1, dated Apr. 18, 2017 (ECF No. 42) Yet the relevant entry, dated March 9, 2013, must be evaluated against other medical records from March 2013 in which onset is again anchored around the time of Petitioner's January incident or December at the earliest. *See, e.g.,* Ex. 7 at 25. This, plus the existence of several records from January 2013 also pinpointing that same period, preponderantly supports a later onset than alleged by Petitioner.

III. Petitioner Has Not Carried His Burden of Proof

A. *Althen Prong One*

Of the three *Althen* prongs relevant herein, the first bears the least on this claim's resolution. Petitioner proposed that the flu vaccine can, via the mechanism of molecular mimicry, cause an autoimmune reaction resulting in ADEM. First Tornatore Rep. at 13; Tr. at 104. Respondent largely ignored this aspect of Mr. Caruso's case – and for good reason, as there is ample existing Program authority (backed up by reliable scientific and medical evidence) that certain vaccines, including the flu vaccine, are reasonably associated with ADEM.[19] Such cases have been litigated fully, and the science offered to support the theory found to be reliable. I am persuaded by such prior decisions, and therefore find that the first *Althen* prong was satisfied in this case.

B. *Althen Prong Two*

Respondent (likely in the hope of establishing an injury that is less associated with the flu vaccine than ADEM), attempted to poke holes in the conclusion that Mr. Caruso suffered from ADEM, arguing that his overall course of illness – a steady progression over a month, beginning more likely than not in late December 2012, a lapse, and then a round of more obviously alarming symptoms sufficiently severe for him to seek treatment – was inconsistent with the commonly-understood acute nature of ADEM. Tr. at 194-99; Leist Rep. at 5. Further, Dr. Leist attributed Petitioner's vision impairment to an optic neuritis diagnosis rather than as further evidence of ADEM. Leist Rep. at 6.

Despite these efforts, preponderant evidence better supports the ADEM diagnosis, at least in a general sense. There is ample record evidence supporting the diagnosis of ADEM over other central nervous system demyelinating diseases like MS (*i.e.* nature of lesions, lack of oligoclonal bands), and the lack of recurrent or new lesions later further supports ADEM. More importantly, Mr. Caruso's treaters embraced ADEM as the proper diagnosis, and it does not appear that any treaters ever adopted an interpretation of the record consistent with what Dr. Leist proposed. Just as the records in this case did not corroborate fact witness testimony about onset, they also do not corroborate Respondent's preferred alternative diagnosis.

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[19] *See, e.g., Brown v. Sec'y of Health & Human Servs.*, No. 09-426V, 2011 WL 5029865, at *41 (Fed. Cl. Spec. Mstr. Sept. 30, 2011) (flu vaccine caused petitioner's ADEM injury); *Daniels v. Sec'y of Health & Human Servs.,* No. 07-462V, 2012 WL 763175 (Fed. Cl. Spec. Mstr. Feb. 16, 2012) (awarding damages after a ruling on entitlement linked ADEM to a flu vaccination); *Hawkins v. Sec'y of Health & Human Servs.*, No. 99-405V, 2009 WL 711931 (Fed. Cl. Spec. Mstr. Feb. 27, 2009) (awarding compensation for ADEM linked to hepatitis B vaccine); *Banks v. Sec'y of Health & Human Servs.*, No. 02-0738V, 2007 WL 2296047 (Fed. Cl. Spec. Mstr. July 20, 2007) (awarding compensation for ADEM linked to MMR vaccine); *Camerlin v. Sec'y of Health & Human Servs.*, No. 99-615V, 2003 WL 22853070 (Fed. Cl. Spec. Mstr. Oct. 29, 2003) (awarding compensation, finding HiB vaccine was a substantial factor related to ADEM); *Kuperus v. Sec'y of Health & Human Servs.*, No. 01-0060V, 2003 WL 22912885 (Fed. Cl. Spec. Mstr. Oct. 23, 2003) (awarding compensation for ADEM linked to DTaP vaccine).

But my *Althen* prong two analysis does not end with the conclusion that Respondent failed in challenging that diagnosis's evidentiary basis – because the most reliable evidence concerning Petitioner's diagnosis is *not* supportive of the causation theory he has (successfully) presented.

As Dr. Tornatore acknowledged, and as the record confirms, Petitioner's illness is best characterized as "atypical ADEM." Tr. at 113-16. Not only was Petitioner outside the usual demographic group experiencing the disease (the very young), but his symptoms did not manifest acutely or suddenly, but instead unfolded more slowly and haltingly. Thus, almost a month passed between the first time Mr. Caruso's wife and daughter observed him displaying an unsteady gait in December 2012 to his performance of the "drunken sailor" walk while shopping on January 25th. Indeed, had I accepted Petitioner's allegation that onset of ADEM occurred in November (and thus closer in time to vaccination), the progression of his symptoms would appear even *less* like classic ADEM, since his medical history would then constitute a series of somewhat mild neurologic symptoms (some weakness, vision difficulty), later leading to more concerning gait dysfunction that slightly improved before progressively worsening a month later.

The above poses a dilemma for evaluating the success of Petitioner's "did cause" evidentiary showing. On the one hand, Mr. Caruso's combination of symptoms, imaging evidence, and other test results led skilled treaters to adopt ADEM as the proper diagnosis, and I find sufficient preponderant evidence supports that conclusion (especially in light of Dr. Dorfman's views expressed in the summer of 2014, which had the benefit of a more expansive record to review than what had been available to initial treaters). But because Petitioner's symptoms were inconsistent with ADEM as it is most commonly understood, it becomes more difficult to simply assume that the same vaccine association applicable to "normal" cases of the disease applies here. Indeed, the literature offered to explain a vaccine's role in causing ADEM largely if not exclusively discusses the acute form of the disease, beginning within a month of infection or vaccination – *not* what the facts show Mr. Caruso experienced. *See, e.g.,* Tenembaum at 1224, Noorbakhsh at 761.

Other special masters have denied compensation on such grounds. Thus, as observed by former Chief Special Master Campbell-Porter in *Stillwell v. Sec'y of Health & Human Servs.,* No. 11-77V, 2013 WL 4540013, at *16 (Fed. Cl. Spec. Mstr. June 17, 2013), *mot. for review den'd,* 118 Fed. Cl. 47 (2014):

> the symptoms of ADEM appear abruptly—that is, between one and two week after the triggering event—in the overwhelming majority of cases . . . Petitioner's symptom onset occurred slowly and well beyond the typical time frame for the vast majority of subjects afflicted with ADEM.

Given the undisputed facts about both ADEM as it is commonly understood and the progression of Mr. Caruso's symptoms, I do not find in favor of Petitioner on this second prong.

Petitioner has not demonstrated that reliable science linking vaccines like the flu vaccine to ADEM applies to his own circumstances, which present a more halting form of the condition.

C. *Althen Prong Three*

Petitioner has offered insufficient evidence, whether in the form of recorded medical documents or literature, supporting his assertion that the timeframe in which his symptoms developed was medically acceptable.

As Respondent has pointed out, the most reliable scientific evidence relating to ADEM's connection to vaccines suggests a far shorter timeframe for onset of the disease than is present under the facts of this case.[20] As noted above, Rowhani-Rahbar stated that the most medically reliable onset between vaccination and ADEM was from 9-30 days. Rowhani-Rahbar at 273. This article allows the possibility of a somewhat longer timeframe—up to 42 days, or six weeks – but is frank in acknowledging that such a time period is less reliable scientifically. Rowhani-Rahbar at 274. But for present purposes, *either* of these timeframes are shorter than what I have found herein to be Petitioner's earliest possible onset in December 2012 (about sixty days post-vaccination).

Rowhani-Rahbar is particularly persuasive with regard to the expected onset for vaccine-induced ADEM. Indeed, it was explicitly relied upon in another case involving both Drs. Tornatore and Leist as experts. In *Day v. Sec'y of Health & Human Servs.*, No. 12-630V, 2015 WL 8028393, at *19-20 (Fed. Cl. Spec. Mstr. Nov. 13, 2015), a case involving neuromyelitis optica occurring three days after a flu vaccine, Dr. Tornatore invoked Rowhani-Rahbar, Noorbakhsh, and Tenembaum in establishing the reliability of a three-day onset based on a molecular mimicry-mediated autoimmune reaction to a vaccine. *Day,* 2015 WL 8028393, at *19. In finding for the *Day* petitioner, Chief Special Master Dorsey characterized the Rowhani-Rahbar intervals as "persuasive." *Id.* at *22. If such a timeframe was deemed reliable for purposes of finding causation when onset fell within it, then it should also have evidentiary heft when applied to a timeframe that falls well *outside* it – as here.

The greater reliability of shorter onset timeframes for vaccine-induced ADEM finds support in the decisions of other special masters. *See, e.g., Daniels v. Sec'y of Health & Human Servs.*, No. 07-462V, 2012 WL 763175 (Fed. Cl. Spec. Mstr. Feb. 16, 2012) (ADEM onset occurring eight days post-vaccination found to be medically acceptable). By contrast, excessively long timeframes have been rejected for many kinds of allegedly vaccine-caused autoimmune processes. *See, e.g., Sullivan v. Sec'y of Health & Human Servs.,* No. 10-398V, 2015 WL 1404957,

[20] I do not find that Poser is as reliable in supporting a longer timeframe, as it involved a different vaccine and was based upon a single instance of onset beyond two months.

at *21 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) (in a claim involving Gardasil vaccine and rheumatoid arthritis where petitioner relied on molecular mimicry as the theory, three months was "too long a timeframe in which onset could have occurred.").

I acknowledge there are reasoned decisions concluding that a two-month onset for ADEM induced by the flu vaccine is medically acceptable. *See, e.g., Brown v. Secretary of Health and Human Services*, No. 09-426V, 2011 WL 5029865, at *42-44 (Fed. Cl. Spec. Mstr. Sept. 30, 2011). However (and putting aside the fact that I am not bound by the decisions of other special masters), two considerations persuade me not to endorse that timeframe in this case. First, *Brown's* findings about timeframe relied on comparing ADEM to other demyelinating diseases like Guillain-Barré syndrome, but (as noted in *Stillwell*) there are sound medical reasons for differentiating the two with respect to onset and timeframe despite their common demyelinating features. *Stillwell*, 2013 WL 4540013, at *21-22 (reliable medical evidence "suggests that ADEM has a much shorter latency period than GBS").[21]

Second, and discussed above in connection with Petitioner's *Althen* prong two showing, the atypical, halting form of ADEM that Mr. Caruso experienced further erodes Petitioner's preponderant showing that a two-month onset (which even *Brown* characterizes as an "outermost time period" (*Brown*, 2011 WL 5029865, at *44)) is in this case medically acceptable. ADEM is most commonly and reliably understood to have an abrupt onset. Noorbakhsh at 761. But here, Petitioner's initial symptoms in December 2012 were mild, with several weeks passing thereafter before his condition became sufficiently acute to impel him to seek medical intervention. The weaknesses of his third prong showing are magnified by the atypical course of his ADEM.

CONCLUSION

The Vaccine Act permits me to award compensation only if a Petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. Here, Petitioner's causation theory depends upon my finding that she experienced a particular injury, but the weight of the evidence does not support that conclusion. Thus—and even if the theory itself has plausibility—there is insufficient evidence to support an award of compensation, leaving me no choice but to hereby **DENY** this claim.

[21] Other special masters have addressed the appropriate timeframe for onset of vaccine-induced ADEM based upon the location of the inflammatory damage in the central nervous system. *See e.g.*, *Kuperus*, 2003 WL 22912885; *Johnson v. Sec'y of Health & Human Servs.,* No. 99-0219V, 2000 WL 1141582 (Fed. Cl. Spec. Mstr. July 27, 2000). In both *Kuperus* and *Johnson*, the relevant onset period was said to be dependent upon the location of the lesions—in the brain (slower onset of no more than 42 days) or in the spinal cord (faster onset of no more than 21 days). *Kuperus*, 2003 WL 22912885, at *10 (awarding compensation by emphasizing that Petitioner's onset did not exceed the 42 day outermost limit for causation), *Johnson*, 2000 WL 1141582, at *6 ("with any infection or immunization, Dr. Weig would look at what occurred 10-21 days before onset. Beyond that there would be no causal relationship."). In this case Mr. Caruso had lesions in both his brain and spinal cord, but even under the longer timeframe applicable to brain lesions his onset would still be too long to satisfy the third *Althen* prong. Ex. 5 at 39-43

In the absence of a timely-filed motion for review (see Appendix B to the Rules of Court), the Clerk shall enter judgment in accord with this decision.[22]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[22] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.